



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/593,814

09/21/2007

Eduardo Marban

001107.00623

5612

22907 7590 10/18/2010

BANNER & WITCOFF, LTD.

1100 13th STREET, N.W.

SUITE 1200

WASHINGTON, DC 20005-4051

EXAMINER

KELLY, ROBERT M

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

10/18/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,814	Applicant(s) MARBAN ET AL.	
	Examiner ROBERT M. KELLY	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-99 is/are pending in the application.
- 4a) Of the above claim(s) 85, 87-93 and 95-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 86, 94, 98 and 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/6/10 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1633

DETAILED ACTION

Applicant's amendment and response of 8/6/10 are entered.

Claims 1-84 are cancelled.

Claims 86-97 are amended.

Claim 98 and 99 are newly presented.

Claims 86-99 remain pending.

Claim Status: Claim 85

Applicant's present amendment lists claim 85 as cancelled, then withdrawn, with the text in the withdrawn claim text. Because the claim is withdrawn, the Examiner has simply considered such to be its status, rather than cancelled, in the interest of compact prosecution. Hence, Claim 85 is still present and withdrawn from examination at this time.

Future non-compliant amendments however, will be responded to as such.

Election/Restrictions

Applicant's election of Group XXVI, and the species of fibroblasts in the reply filed on 2/9/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Art Unit: 1633

Claims 85, 87-93, 95-97 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/9/10.

Claims 86 and 94, 98 and 99 are presently considered with respect to the elected species of fibroblasts.

Drawings

In light of the amended drawings supplied on 8/6/10, the objections to the drawings are withdrawn.

Specification

In light of the amendment to the specification of 8/6/10, the objections to the specification are withdrawn.

Claim Objections

In light of the amendments, the objections to the claims are withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

Art Unit: 1633

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

In light of further consideration, the rejections of Claims 86 and 94 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 19, 34 and 35, and all claims generically of U.S. Patent No. 6,124,620, are withdrawn.

To wit, the patent is not to Applicant, but another person with the surname Abraham.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86, 94, 98 and 99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for comprising new matter. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 86, 94, 98, and 99, claim or encompass the generic decrease of APD80 in cells expressing connexin, as evidenced by Claim 99, and its separate dependency from Claim 86.

Applicant's sole disclosure providing possession of anything having to do with APD80 is paragraph 49, Example 5, of Applicant's specification, which describes a specific SkM-NRVM co-cultured cells, expressing Cx43 from a specific lentivirus and promoter, in which ADP80 was decreased by 20% compared to distinctly-transformed co-cultures (paragraph 49). Such disclosure does not appear to provide support for a generically-transformed fibroblast, expressing any connexin, from any lentivirus, with any promoter, to provide ADP80 decreases of 20% or more. Still further, the paragraph, being an example, and not provide a generic possession of the generic embodiment claimed, simply does not evince that Applicant had possession of the claimed generic embodiment at the time of filing.

Also, as shown by the separate dependency of Claim 98, the claims are drawn to or encompass a generic increase in conduction velocity of fibroblasts.

Art Unit: 1633

However, while the specification appears to evince generic possession of decreases in conduction velocity, for a coculture of myoblasts and myocytes (e.g., paragraph 005 of the specification publication), the discussion of found results repeatedly is found in, e.g., Example 5 and is coupled to the same 20% decrease in APD80, and the decrease is specifically 30% decrease.

Moreover, the Art fails to describe this attribute on cultures in general, and hence, does nothing to provide for possession of the invention.

Hence, the Artisan would not have understood Applicant to have been in possession of the invention as claimed at the time of filing, for these results generically and/or separately from each other.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejections of Claims 86 and 94 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,317,950 to Lee are withdrawn, because Lee does not teach lentivirus vectors.

Art Unit: 1633

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 86, 94, 98, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,317,950 to Lee and the general knowledge in the Art, as demonstrated by U.S. Patent No. 4,927,843 to Teitz and U.S. Patent No. 5,856,185 to Gruber, et al.

Lee claims cardiac stimulation systems (Claim 1), which comprise fibroblasts (Claim 20), adapted to express connexin (Claim 21). The specification teaches that one construct to express the connexin is expressed off a lenti-virus promoter (Section entitled "Constructs for Connexin Nucleic Acids, paragraph 3). Further Lee teaches that the constructs can be expressed off a vector of choice, depending on whether integration or episomal location is wanted (e.g., Id.). However, Lee does not teach the specific use of lentiviral vectors.

Teitz teaches fibroblast cells which are infected with EIAV, one lentivirus (Section "D." Subsection "a. Effect of drugs against EIAV"). Gruber teaches that fibroblasts can be transformed with HIV (e.g., Section Labelled "C. Extracorporeal Treatment of Human, Chimpanzee and Macaque Cells to Induce Expression of Vector Encoded Proteins"). These examples demonstrate that it is known that to utilize lentivirus to infect fibroblasts. In fact, it is well known that Lentiviruses are especially good at transforming non-dividing cells as well as dividing cells, and hence, it should be good at transforming any fibroblast.

Art Unit: 1633

Moreover, the specific properties of an obvious composition are not found patentable unless the finding is unexpected (i.e., the Art specifically did not believe it would occur) or surprising (i.e., so far out of the understanding of the Artisan, that it just would not be believed to occur).

Hence, at the time of invention, it would have been obvious to make the invention. The Artisan would do so to transform the fibroblasts of Lee, and would have a reasonable expectation of success, as the elements are utilized for their art-recognized purposes.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633